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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/033,350	11/02/2001	Robert D. Klein	GENENT.48CP1C1	9833

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EXAMINER	
HAYES, ROBERT CLINTON	
ART UNIT	**PAPER NUMBER**
1647	

DATE MAILED: 10/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/033,350	KLEIN ET AL.	
	Examiner	Art Unit	
	Robert C. Hayes, Ph.D.	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 November 2001*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-60* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *2-60* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 2-10, 41-46 & 59-60, drawn to GDNF receptor polypeptides, chimeric receptor molecules, compositions thereof, classified in class 530, subclass 350.

II. Claims 23-31 & 47-58, polynucleotides encoding GDNF receptor polypeptides, vectors, host cells and method for producing the polypeptide, classified in class 435, subclass 69.1.

III. Claims 11-12 & 14-15, drawn to methods of identifying and purifying molecules that bind GDNFRα, classified in class 435, subclass 7.1.

IV. Claim 13, drawn to methods of identifying molecules that activate GDNFRα, classified in class 435, subclass 7.21.

V. Claims 16-19, drawn to antibodies that bind GDNFRα, and compositions thereof, classified in class 530, subclass 387.1.

VI. Claim 20, drawn to methods using GDNFRα agonist antibodies to activate GDNFRα, classified in class 435, subclass 69.

VII. Claim 21, drawn to a method of modulating a physiological response of a cell to GDNF comprising contacting a cell with GDNFRα, classified in class 514, subclass 12.

VIII. Claim 22, drawn to methods of detecting GDNFRα in a test sample comprising use of antibodies, classified in class 435, subclass 7.2.

IX. Claim 32-33, drawn to nonhuman transgenic animals, classified in class 800, subclass 2.

X. Claim 34-37, drawn to methods of treating kidney disease comprising administering to a patient a therapeutically effective amount of GDNF, GDNFRα, or GDNF agonists, classified in class 514, subclass 2.

XI. Claim 38-40, drawn to methods of treating enteric nervous system-related disorders comprising administering to a patient a therapeutically effective amount of GDNF, GDNFRα, or GDNF agonists, classified in class 514, subclass 2.

2. The inventions are distinct, each from the other because of the following reasons:

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different products, restriction is deemed to be proper, because these products appear to constitute patentably distinct inventions for the following reasons:

Groups I-II, V & IX are directed to products that are physically and functionally distinct, involving proteins, nucleic acids, antibodies and transgenic animals. Additionally, all of these products can be prepared by different processes, such as though chemical synthesis or isolation from natural sources using various isolation/purification procedures. For example, the proteins of Group I and antibodies of Group V are fundamentally different molecules than the nucleic acid molecules of Group II, which in turn can be used to clone proteins, detect cells that express the protein, or used as therapeutic agents in gene therapy. Although the antibodies of Group V can be used in isolating the proteins of Group I, the antibodies of Group V can be generated by

immunizing animals with a small synthetic portion of the full length protein, and can be used diagnostically in other ways, such as in affinity chromatography or in immunoassays, or as therapeutic agents themselves. The proteins of Group I can be utilized in making the antibodies of Group V, but not vice versa. The transgenic animals of Group IX can be used to study the effects of expression and activity of the recombinant DNA molecules of Group II, but do not necessarily contain the same isolated DNA molecules/vector sequences of Group II. Moreover, the transgenic animals of Group IX are not required in the products of Groups I-II & V, and vice versa. In addition, neither the proteins of Group I nor the antibodies of Group V require the vectors and host cells of Group II, and vice versa. It is pointed out that there is a proper distinction between these groups, since each product is not required in order for the other to exist. Thereby, these groups are distinct and separable for the reasons stated.

Groups I and III-IV, VI-VIII, X & XI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the proteins of Group I can be used in other materially different methods, such as to generate antibodies to GDNFRα. In contrast, the methods of treating patients or cells with GDNF-related proteins in Groups VII, X & XI require cells or patients to treat, as well as appropriate administration protocols, while the assay methods of Groups III, IV, VI & VIII require other molecules or antibodies, as well as binding or activation protocols; none of which are required in the products of Group I.

Although there are no provisions under the section for "Relation of Inventions" in M.P.E.P. 806.05 for inventive groups that are directed to different methods, restriction is deemed proper because these methods appear to constitute patently distinct inventions for the following reasons:

Groups III-IV, VI-VIII and X-XI are directed to methods of detecting the binding of molecules or antibodies with GDNFα, the activation of GDNFRα, or methods of treating cells or patients with specific disease states. Each of these methods require physically and functionally distinct elements, have different starting materials, different method steps, and have different goals. For example, the methods for detecting binding or activation of the GDNFα receptor protein of Groups III, IV & VI are distinguished from the treatment methods of Groups VII, X & XI in that the assay methods of Groups III, IV & VI require labeling reagents, assay protocols and/or separate binding molecules or antibody agonists, unlike the methods of treating cells or patients, which alternatively require administration protocols, patients with specific disease states, GDNF or GDNF agonists, and/or assayable physiological responses not required in the assay methods of Groups III, IV and VI, and vice versa. The methods for identifying and purifying molecules that bind GDNFRα of Group III are distinguished from the methods of activating GDNFRα with different molecules (Group IV) or antibody agonists (Group VI) due to the different purification and binding protocols required in the method of Group III, versus the activation protocols required in the methods of Groups IV and VI, and vice versa. Likewise, the treatment methods of Groups VII, X and XI are distinguished in that different patients with different disease states are required to be treated in the methods of Groups X and XI, and vice versa, whereas only individual cells with a measurable physiological response are required in the

treatment method of Group VII, and vice versa. These inventions are, therefore, patentably distinct, since one is not required for the other.

Because these inventions are distinct for the reasons given above, they have acquired a separate status in the art as shown by their different classification, and the lack of coextensiveness of the search and examination for each group would constitute an undue burden on the examiner to search and consider all the separable groups with their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

3. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

4. Lastly, note that *In re Ochiai*, 71 F.3d 1565, 37 USPQ2d 1127 (Fed. Cir. 1995) and *In re Brouwer*, 77 F.3d 422, 37 USPQ2d 1663 (Fed. Cir. 1996) addressed the issue of whether an otherwise conventional process could be patented if it were limited to making or using a nonobvious product.

> In situations where product and process claims drawn to independent and distinct inventions are presented in the same application, an applicant may be called upon under 35 U.S.C. §121 to elect claims to either the product or process. The claims to the non-elected invention will be withdrawn from further consideration. However, in the case of an elected product claim, when a product claim is found allowable, withdrawn process claims which depend from or otherwise include all the limitations of an allowable

product claim will be rejoined. Withdrawn process claims not commensurate in scope with an allowable product claim will not be rejoined. In the event of rejoinder, the rejoined process claims will be fully examined for patentability. If the application containing the rejoined claims is not in condition for allowance, the subsequent Office action may be made final, or, if the application was already under final rejection, the next Office action may be an advisory action.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (571) 272-0885. The examiner can normally be reached on Monday through Thursday, and alternate Fridays, from 8:30 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on (571) 272-0961. The fax phone number for this Group is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert C. Hayes, Ph.D.
September 30, 2004

ROBERT C. HAYES, PH.D.
PATENT EXAMINER